IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: METOPROLOL SUCCINATE END-PAYOR ANTITRUST LITIGATION	)	C.A. No. 06-71 (GMS)
THIS DOCUMENT RELATES TO: ALL ACTIONS	)	

DEFENDANTS' REPLY BRIEF IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT OR, IF THAT MOTION IS DENIED, TO STAY THIS ACTION

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INTRODUCTION

Plaintiffs, in their brief in opposition to AstraZeneca's motion to dismiss, fail to come to terms with the fundamental principle that an independent bar to competition in the relevant market breaks the causal connection between an alleged antitrust violation and plaintiffs' alleged injuries.

In its opening brief, AstraZeneca showed that such an "independent bar" exists in this case – the lack of Food and Drug Administration ("FDA") tentative approval of an Abbreviated New Drug Application ("ANDA") from any generic manufacturer while the automatic 30-month stay was in effect. That lack of tentative approval – which plaintiffs admit – means that the 30-month stay triggered by the filing by AstraZeneca of the patent litigation against the generic pharmaceutical companies did not adversely affect competition in the alleged relevant market. That is so because the FDA is unrestricted in its ability to grant tentative approval while the stay is in effect. If an ANDA actually met the requirements for FDA approval during the pendency of the stay, the FDA could have granted it tentative approval. Had any of the generic filers in this case received tentative approval while the stay was in effect, plaintiffs would have an argument that AstraZeneca's lawsuit caused their alleged injuries. However, the lack of tentative FDA approval created an independent bar to competition in the market, regardless of AstraZeneca's alleged conduct. The principle that an independent bar breaks the causal connection has been squarely recognized by the Third Circuit, and it governs this case. *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256 (3d Cir. 1998).

In response, plaintiffs argue that the difference here is that AstraZeneca's conduct delayed the possibility of FDA tentative approval. Under plaintiffs' theory, both the generic manufacturers who filed ANDAs and the FDA itself effectively take a "time-out" when patent litigation is filed by a brand-name manufacturer and direct their resources away from the ANDA approval process.

As AstraZeneca showed in its opening brief, this allegation is unsupportable and belied by case law showing that generic manufacturers do receive tentative approval while the automatic stay is in effect. Although plaintiffs fall back on the refrain that this Court must accept their allegations as true, the Court need not credit unsupportable allegations. ***See, e.g., Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.***, 113 F.3d 405, 417 (3d Cir. 1997) (court need not credit "unsupported conclusions and unwarranted inferences" or allegations that are belied by other factual allegations and the law).

Plaintiffs' allegations are unsupportable for several reasons. First, the FDA has stated that the tentative approval process contemplates approval irrespective of whether a stay is in effect. Second, the FDA generally prioritizes ANDAs based on the timing they are submitted by generic manufacturers. Third, there are numerous examples of the FDA granting tentative approval of an ANDA while a 30-month stay is in effect. Fourth, the 2003 amendments to the Hatch-Waxman Act compel ANDA filers to pursue tentative approval and the FDA to consider and grant tentative approval to qualifying ANDAs even when a stay is in effect. Finally, plaintiffs submit a document, as Exhibit B to their opposition brief, showing that on July 31, 2006, well after the stay had been lifted and the district court patent litigation completed, the FDA granted final approval to the ANDA of Sandoz, Inc. (the successor of Eon Labs, Inc.), which sought to market generic metoprolol succinate at the 25 mg dosage level.[1] That document suggests that, in this case, at least one of the generic manufacturers did pursue tentative FDA approval during the stay.

[1] Despite having final FDA approval at the 25 mg dosage level, Sandoz has still not launched its generic version. Thus, it is Sandoz's decision not to enter the market that currently prevents plaintiffs from purchasing generic metoprolol succinate. Moreover, in the same July 31, 2006 FDA letter, the FDA granted tentative approval to Sandoz at other dosage levels, but those approvals cannot become final because the first ANDA filers at those dosage levels, Andrx and KV, still have not obtained FDA approval. Andrx's and KV's continuing failure to receive FDA approval prevents Sandoz from entering those markets.

Plaintiffs also float the notion that unknown generic manufacturers were dissuaded from developing and seeking approval of generic metoprolol succinate. Of course, these hypothetical manufacturers would also need FDA approval for their hypothetical ANDAs. This highly speculative allegation – which would apply equally to any Hatch-Waxman case – is precluded by *West Penn Power*, which held that "the appellants cannot foist their version of what might have been on the court under the rubric of antitrust injury. The presence of the regulatory scheme and need for approval . . . cuts the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise." 147 F.3d at 267-68.

Plaintiffs also argue that there are two "facets" of their claims – independent of their allegations regarding the 30-month stay – that require denial of the motion to dismiss. Plaintiffs are mistaken. First, they contend that AstraZeneca's procurement of the relevant patents and the listing in the Orange Book provide a basis for the antitrust claim. This argument is foreclosed by *Walker-Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), which permits suits against patent holders only where there is an attempt to enforce the patent. Here, without the patent litigation, and the attendant 30-month stay, there is no antitrust claim, and plaintiffs do not cite any case holding otherwise. Plaintiffs' second argument is that there would be no 180-day period of exclusivity in the absence of AstraZeneca's alleged conduct. But this claim is not ripe. Currently, only one generic manufacturer has received FDA approval to market a generic version of metoprolol succinate at one dosage level, and that manufacturer is not entitled to the 180-day exclusivity period and is not yet on the market in any event. Because the 180-day exclusivity period has not been granted to any generic company, the plaintiffs could not have been damaged by the possibility that the period will exist in the future for any dosage level.

In the absence of any supportable allegations that AstraZeneca's conduct actually delayed FDA tentative approval, the FDA's failure to provide tentative approval is an independent cause that fully accounts for the absence of a generic version of metoprolol succinate from the market. Because plaintiffs' allegations are contradicted by the plaintiffs' own evidence and are otherwise insufficient as a matter of law, the Complaint should be dismissed.

If it is not dismissed, this action certainly should be stayed until the entry of a final decision in the patent litigation. AstraZeneca demonstrated in its opening brief that there are compelling reasons for a stay under the criteria this Court employed in *In re Pharmastem Therapeutics, Inc. Patent Litigation*, No. 05-md-1660 GMS (D. Del. Oct. 6, 2005). Plaintiffs do not argue that they would suffer undue prejudice from a stay and do not challenge the fact that a stay is favored where, as here, the litigation is at an early stage. Instead, they claim that AstraZeneca has not established its chances of success on the patent litigation appeal. The merits of the case will be fully addressed on appeal. Here, as in *Pharmastem*, the outcome of the appeal – which has been fully briefed and awaits only oral argument and a decision – may resolve or simplify the issues in this case, and thus the action should be stayed if the motion to dismiss is denied.

ARGUMENT

I. PLAINTIFFS ARE UNABLE TO ESTABLISH ANTITRUST STANDING

A. Plaintiffs Cannot Establish That the Alleged Conduct Delayed Tentative FDA Approval

Plaintiffs' Complaint acknowledges that a company may not begin selling a drug without FDA approval. (Compl., D.I. 13, ¶¶ 41, 55.) Plaintiffs also agree that the FDA was empowered to grant tentative FDA approval during the pendency of the 30-month stay. The question this motion

to dismiss raises is: does the Complaint reasonably allege facts that could support allegations that AstraZeneca is responsible for the lack of tentative FDA approval of any generic drug application while the 30-month stay was in effect? If not, then the lack of tentative FDA approval is an independent and absolute bar on competition in the alleged relevant market which "cuts the causal chain" between AstraZeneca's alleged antitrust violations and plaintiffs' alleged injuries. *See West Penn Power*, 147 F.3d at 268. Plaintiffs' attempts to hold AstraZeneca responsible are without foundation, legally insufficient, and contradicted by plaintiffs' own documents.

Plaintiffs point to three allegations that supposedly describe the ways in which AstraZeneca specifically delayed the FDA approval process. First, as a result of the 30-month stay, the FDA allegedly shifted its limited resources away from the pending ANDAs for metoprolol succinate. Second, also because of the stay, the generic manufacturers allegedly redirected their attention and resources away from their ANDAs. Finally, other unknown generic competitors were allegedly dissuaded from filing ANDAs. This Court should not accept as true "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res.*, 113 F.3d at 417, and all of the plaintiffs' allegations are unsupportable.[2] Moreover, where plaintiffs' antitrust standing is at issue, the Third Circuit has said that the "courts have an obligation in matters before them to view the complaint as a whole and to base rulings not upon the presence of mere words but, rather, upon the presence of a factual situation which is or is not justiciable." *West Penn Power*, 147 F.3d at 263.

[2] Contrary to plaintiffs' repeated complaints, AstraZeneca is not asking this Court to accept its own facts. (*See, e.g.*, D.I. 28 at 22.) As plaintiffs are no doubt aware, the Court must determine whether the alleged facts include unsupported conclusions or unwarranted inferences and also whether the allegations are contradicted by other allegations in the Complaint or documents on which plaintiffs rely. Where, as here, the allegations are not supported or contradicted, the Complaint is not legally sufficient and should be dismissed under Rule 12(b)(6).

1. <u>The Resources of the FDA</u>

Plaintiffs contend that AstraZeneca's prosecution of the patent litigation, and the ensuing automatic 30-month stay, caused the FDA to divert its attention and resources away from the ANDAs for generic metoprolol succinate. (D.I. 28 at 17-18.) But it is well-recognized that the Court need not accept baseless allegations, *Schuylkill Energy Res.*, 113 F.3d at 417, or ones contradicted by information the Court can consider on a motion to dismiss, *see* D.I. 28 at 8 n.2.

There are several reasons why this allegation cannot be credited. First, the FDA's own explanation of the tentative approval process contemplates approval irrespective of whether a stay is in effect. As the FDA has stated publicly, "If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved." *See* FDA, Center for Drug Evaluation & Research, Drugs@FDA – Glossary of Terms, http://www.fda.gov/cder/drugsatfda/glossary.htm. (Ex. A.)

Second, a document plaintiffs cite reveals that the FDA does not discriminate between ANDAs eligible only for tentative approval and those that could received final approval. In a published report, the FDA emphasized that "[t]he only difference between a full approval and a tentative approval is that the final approval of these applications is due to existing patent or exclusivity on the innovator drug product." FDA Center for Drug Evaluation and Research, *2004 Report to the Nation*, at 29 [hereinafter "*2004 Report to the Nation*"], *available at* http://www.fda.gov/cder/reports/rtn/2004/Rtn2004.pdf. (D.I. 28 at 17 n.8.) This explanation is

consistent with AstraZeneca's argument and contradicts the notion that the FDA acts differently depending on whether a litigation stay is in place. *See Improving Access to Generic Drugs: Hearing Before the Senate Special Comm. on Aging*, 109th Congress (July 20, 2006) ("*[The Office of Generic Drugs] generally maintains a 'first-in, first-reviewed' policy for ANDAs*. FDA instituted this generic drug review priority to ensure the integrity of the approval process." (emphasis added)), *available at* http://www.hhs.gov/asl/testify/t060720.html (Ex. B).

Third, consistent with the FDA's statements, and as AstraZeneca demonstrated in its opening brief (D.I. 25 at 20-21), there are numerous examples of the FDA granting tentative approval of an ANDA while a 30-month stay is in effect. *See, e.g.*, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 902 (6th Cir. 2003) ("On September 15, 1997, the FDA tentatively approved Andrx's ANDA, indicating that it would be finally approved as soon as it was eligible, either upon expiration of the thirty-month waiting period in early July 1998, or earlier if the court in the patent infringement action ruled that the '584 patent was not infringed."); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1372 & n.2 (Fed. Cir. 2002) ("In September 2000 Andrx had received tentative approval of its ANDA from the FDA" pending the February 25, 2001 expiration of the stay.); *Elan Corp., PLC v. Andrx Pharms., Inc.*, 272 F. Supp. 2d 1325, 1330 (S.D. Fla. 2003) ("The FDA granted the Andrx ANDA tentative approval on March 17, 2000" while patent litigation continued.); *In re Relafen Antitrust Litig.*, 286 F. Supp. 2d 56, 60 (D. Mass. 2003) ("On August 8, . . . the FDA issued tentative approval to Eon's . . . generic nabumetone product[], but the FDA withheld final approval until the conclusion of the thirty-month stay period."). Plaintiffs suggest that, in these cases, "other, unknown factors must have influenced [the] FDA in those particular instances" (D.I. 28 at 19 n.11), but this explanation is hollow. If the FDA is distracted

or otherwise delays the FDA approval process while the stay is in effect, as plaintiffs suggest, then there would be no reason for the FDA to have tentatively approved the ANDAs in these (and other) cases. *See 2004 Report to the Nation*, at 29 (reporting that, in 2004, FDA gave tentative approval to 95 ANDAs).

Fourth, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 compels the FDA to consider and grant tentative approval to qualifying ANDAs even when a stay is in effect. Among other provisions, the 2003 Act amended the Hatch-Waxman Act to provide that a first ANDA filer will forfeit the 180-day exclusivity period if the ANDA filer fails to receive tentative approval within 30 months of filing its ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv). This is a substantial penalty for a generic company, and the possibility of such penalty compels the FDA to give consideration to ANDAs during this period. In this case, Sandoz's ANDA filing was subject to the 2003 amendments, and the FDA recognizes that Sandoz is subject to the forfeiture provision. According to the FDA, although Sandoz was the first ANDA filer at the 25 mg dosage level, "Sandoz failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed." (D.I. 28, Ex. B, at 3.) Therefore, as explained by the FDA in its letter to Sandoz, if another generic receives FDA approval at the 25 mg dosage level, Sandoz may not enjoy the 180-day period of exclusivity (assuming Sandoz ever actually launches a generic version of metoprolol succinate). (*Id.*) Because the law penalizes ANDA filers who do not obtain tentative approval during the 30 months, it is illogical to assume, as plaintiffs do, that the FDA will not give appropriate consideration to ANDAs while a stay is in effect.

Finally, the FDA approval letter to Sandoz further suggests that AstraZeneca did not delay FDA approval.[3] That letter reveals that Sandoz made four amendments to its original ANDA and sent the FDA five letters prior to final FDA approval. (D.I. 28, Ex. B, at 1.) One amendment and four letters were submitted well before the stay was lifted, which suggests that both the FDA and Sandoz were devoting resources and attention to the approval process while the stay was in effect.

2. <u>The Generic Manufacturers' Resources</u>

Plaintiffs next allege that the generic manufacturers who filed ANDAs shifted resources away from the FDA approval process as a result of the 30-month stay. (D.I. 28 at 16-17.) However, as described above, there are several reasons that this allegation is unsupportable. First, ANDA filers actually do pursue – and receive – tentative approval while a stay is in effect. *See supra* pp. 7-8. Second, generic filers such as Sandoz that are subject to the 2003 amendments to Hatch-Waxman must receive tentative approval to secure a 180-day period of generic exclusivity. *See supra* p. 8. Third, the FDA approval letter sent to Sandoz suggests that, in this case, Sandoz did pursue FDA approval during the 30-month stay period. *See supra* p. 9. AstraZeneca's opening brief contains additional reasons this allegation should not be credited. (D.I. 25 at 19-21).

Plaintiffs point to two cases which they argue adopted their view of the implications of patent litigation on generic manufacturer incentives. (D.I. 28 at 16-17 (citing *Bristol-Myers Squibb v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 545 (D.N.J. 2000); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 & n.8 (E.D. Pa. 2003)).) In *Wellbutrin*, the court did not refer to or discuss the incentives of generic manufacturers to obtain tentative approval during the

[3] AstraZeneca explained in its opening brief that FDA approval subsequent to lifting of the stay has no impact on the analysis because post-stay approval means that something other than the alleged conduct caused the lack of approval in the interim. (D.I. 25 at 9.)

30-month stay, and is therefore inapposite. In *Ben Venue*, the court credited the generic company's representation at oral argument that "generic manufacturers have had little practical incentive to pursue even conditional [FDA] approval." 90 F. Supp. 2d at 545. As AstraZeneca explained in its opening brief, there are several reasons why generic manufacturers have every incentive to pursue tentative FDA approval during the litigation. (D.I. 25 at 19-21.)[4] In addition, *Ben Venue* was decided before the enactment of the 2003 amendments to the Hatch-Waxman Act, which, among other things, provide for the forfeiture of the 180-day exclusivity period in the event the ANDA filer does not receive tentative approval during the 30-month stay. That is the provision the FDA refers to in the Sandoz approval letter and explains why Sandoz was highly motivated to obtain tentative FDA approval. *See supra* p. 8. Because *Ben Venue* pre-dated this change to the law, the reference to the lack of incentives for generic manufacturers is, at best, outdated. And because the Sandoz letter contradicts plaintiffs' allegations that the generic companies do not pursue tentative FDA approval while a stay is in effect, those allegations should not be credited.

3. Hypothetical Competitors Should Not Be Considered

In a footnote, plaintiffs also allege that certain unknown generic manufacturers might have been dissuaded from developing and seeking approval of generic metoprolol succinate. (D.I. 28 at

[4] Plaintiffs take issue with AstraZeneca's argument that generic ANDA applicants would prefer to obtain tentative FDA approval expeditiously so they will not potentially lose any portion of the 180-day period of generic exclusivity. (D.I. 28 at 19.) AstraZeneca's original argument is correct. Each of the three ANDA applicants in this case are the first ANDA filers at different dosage levels, so all are in line to obtain exclusivity if FDA approval is secured. That does not mean that the 180 days would be free from competition. For Sandoz, which is subject to the 2003 amendments, the exclusivity period may be forfeited because it did not receive tentative approval during the 30-month stay period. *See supra* p. 8. That is a tremendous incentive to obtain tentative approval as expeditiously as possible. If the exclusivity period is forfeited, Sandoz will have "exclusivity" only to the extent no other generics are approved at that dosage level. Thus, Sandoz was further incentivized to obtain approval as soon as possible, to enter the market before other potential competitors could, even though it was the first filer.

21 n.12.) This allegation is far too speculative to support antitrust standing. *West Penn Power*, 147 F.3d at 267-68; *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 181 (3d Cir. 1997); *Daniel v. Am. Bd. of Emergency Med.*, 428 F.3d 408 (2d Cir. 2005); *Vinci v. Waste Mgmt., Inc.*, 80 F.3d 1372, 1375 (9th Cir. 1996). Of course, these hypothetical manufacturers would need FDA approval for their hypothetical ANDAs, and because there is no allegation that these "filers" ever received FDA approval (nor could there be), plaintiffs' allegation is unsupportable.

This Court is bound to follow *West Penn Power*, a case in which the Third Circuit held that if the court can "determine from the face of the complaint" that the potential competitor did not have regulatory approval to enter the market, then the claimed antitrust violation is not actionable. 147 F.3d at 266. *West Penn Power* also held that "the appellants cannot foist their version of what might have been on the court under the rubric of antitrust injury. The presence of the regulatory scheme and need for approval . . . cuts the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise." 147 F.3d at 267-68.

B. <u>Plaintiffs Misperceive the Causation Requirement</u>

Plaintiffs also argue that, separate from the specific allegations of delay in the FDA approval process, AstraZeneca caused the alleged injuries because AstraZeneca itself triggered the regulatory process (D.I. 28 at 13-14) and because AstraZeneca's conduct is at least a material cause of the alleged injuries. Neither argument withstands scrutiny.

First, the relevant part of the regulatory process at issue is FDA approval. Plaintiffs do not argue – nor could they – that AstraZeneca's conduct triggered the need for FDA approval. Under 21 U.S.C. § 355(a), "[n]o person shall introduce or deliver for introduction into interstate

commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." Subsection (b), in turn, concerns New Drug Applications, and subsection (j) concerns ANDAs. Under either section, FDA approval is required before a drug may be marketed.

Second, plaintiffs argue that, even if FDA approval were the cause of their injuries, AstraZeneca could still be liable because its alleged conduct is a "material cause" of plaintiffs' injuries. (D.I. 28 at 22-23.) The alleged conduct cannot be a material cause of an injury, however, if an independent cause fully accounts for the claimed injury. Here, the lack of tentative FDA approval while the stay was in place is such an independent cause. *See, e.g.*, *West Penn Power*, 147 F.3d at 256. According to the leading treatise, "[A] plaintiff cannot be injured in fact by private conduct excluding it from the market when a statute prevents the plaintiff from entering that market in any event." 2 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 338b, at 320 (2d ed. 2000); *see also Axis v. Micafil*, 870 F.2d 1105 (6th Cir. 1989) (no standing for plaintiff unable to obtain government-required license to enter market from which defendant allegedly excluded him).

C. The Case Law Favors Dismissal

Plaintiffs place significant reliance on two district court cases from other courts in the Third Circuit, *Ben Venue* and *In re Wellbutrin*. As discussed earlier, *supra* pp. 9-10, those cases are inapposite. *Wellbutrin* does not even discuss tentative FDA approval and *Ben Venue* predates the 2003 amendments to the Hatch-Waxman Act, which provide significant incentives for generic manufacturers to obtain, and potential penalties for the failure to obtain, tentative FDA approval. In addition, because the Sandoz approval letter demonstrates that a generic manufacturer in this

case actively sought tentative FDA approval, the *Ben Venue* court's acceptance of a general allegation that generics are disincentivized from seeking such approval is irrelevant here.

Plaintiffs attempt to distinguish *West Penn Power*, where the Third Circuit held that the plaintiff could not show antitrust injury because state regulations barred one of the defendant utility companies from competing in certain areas at that time without regulatory approval. *Id.* at 263. The lack of approval was an intervening cause, the court reasoned, which "cuts the causal chain" between the alleged injury and the alleged antitrust violation. *Id.*

Plaintiffs do not and cannot successfully attack this core holding of the Third Circuit. Instead, they try to distinguish the case and limit it to its facts. For example, plaintiffs point out that the *West Penn Power* court noted that there were no allegations in the complaint which would permit the court to speculate as to the likelihood of regulatory approval. (D.I. 28 at 26 n.15 (citing *West Penn Power*, 147 F.3d at 267-68).) Plaintiffs point to allegations in their Complaint which claim there would have been earlier regulatory approval here absent the alleged conduct. (*Id.*) Plaintiffs' argument does not work, however, because it is clear there would not have been earlier approval absent the challenged conduct, because there was no tentative FDA approval while the stay was in effect. The lack of tentative FDA approval during the stay is conclusive evidence that the alleged conduct had no bearing on the timing of the approval.

Plaintiffs also attempt to limit *West Penn Power*'s holding to heavily regulated electric utility monopolies. (D.I. 28 at 24-25.) The selective passages plaintiffs include distort the Third Circuit's holding. Rather than limiting the case to utilities, the Court made clear that if the utilities were deregulated as then planned, the antitrust standing analysis would be different. The difference between the two scenarios is that deregulated utilities would no longer need

government approval to enter a market. As the court wrote, "Had the ability of the utilities to serve various customers in various regions not been subject to approval of the [regulatory commission], our standing analysis would be radically different." 147 F.3d at 269. Thus, the court did not limit its holding to utilities, but to industries in which government approval is required for market entry.

The Third Circuit has subsequently read *West Penn Power* to stand for the broader proposition that "because an intervening regulatory scheme precluded the companies from competing, . . . the [alleged conduct] was not the cause of the injury." *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 401 (3d Cir. 2000). Similarly, *West Penn Power* has been cited numerous times as support for the proposition that "[a]ntitrust injury . . . must be caused by something other than the regulatory action limiting entry to the market." *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003), *aff'd*, 429 F.3d 370 (2d Cir. 2005); *accord Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 23-25 (D. Mass. 2000); 2 Areeda & Hovenkamp, Antitrust Law ¶ 338b, at 320.

West Penn Power cannot be distinguished or limited in the ways plaintiffs suggest. It controls this case and requires dismissal of the plaintiffs' Complaint.

D. Plaintiffs' Policy Argument Is Misplaced

In last-ditch effort to save their Complaint, plaintiffs argue that a decision in favor of AstraZeneca would make antitrust standing a matter of chance. (D.I. 28 at 23-24.) In reality, AstraZeneca is simply asking the Court to dismiss a complaint where the allegations and documents on which plaintiffs rely demonstrate that the lack of tentative FDA approval during the pendency of the stay is a reason independent of any alleged conduct by AstraZeneca for the

plaintiffs' alleged injuries. Such a decision is consistent with fundamental principles of antitrust law. Indeed, adopting plaintiffs' generic arguments about what could happen differently in the FDA approval process would eviscerate the causation requirement in every Hatch-Waxman Act case.

Plaintiffs cite *Ben Venue Labs* in support (D.I. 28 at 23), but the passage from that case suggests that the Court was concerned about the interplay between FDA approval and the antitrust litigation itself. The court was concerned that if "the patentee beat the applicant to the punch by filing a motion to dismiss before FDA approval, the generic maker would be denied antitrust standing." 90 F. Supp. 2d at 545. Here, there is no similar concern because the litigation stay was lifted well in advance of any FDA approval, and AstraZeneca's only argument is that the generic manufacturers' failure to obtain tentative approval during that stay compels the conclusion that plaintiffs lack antitrust standing.

II. PLAINTIFFS' OTHER PURPORTED FEDERAL ANTITRUST CLAIMS ARE WITHOUT BASIS

Plaintiffs argue that there are two "facets" of their claims – independent of their allegations regarding the 30-month stay – that require denial of the motion to dismiss. First, they contend that AstraZeneca's procurement of the relevant patents and the listing in the Orange Book provide a basis for an antitrust claim. Second, plaintiffs claim that no generic manufacturer would be entitled to an 180-day period of market exclusivity in the absence of AstraZeneca's alleged conduct. Neither argument states an antitrust claim.

A. There Is No Antitrust Claim in a Patent Case Absent Enforcement

Without citing a single case, plaintiffs assert an antitrust claim based solely on AstraZeneca's alleged pre-enforcement conduct – its procurement of the relevant patents and the

listing in the Orange Book. (D.I. 28 at 31-32.) But the law is well established that there is no antitrust liability for pre-enforcement conduct.

The Supreme Court has held that the fraudulent acquisition of a patent *followed by* a suit to enforce it can, in certain circumstances, provide the basis for a claim under § 2 of the Sherman Act. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 174 (1965). As the Federal Circuit has said, "Mere procurement of the patent, whatever the conduct of the Applicant in the procurement, cannot without more affect the welfare of the consumer and cannot itself violate the anti-trust laws." *FMC Corp. v. Manitowoc Corp.*, 835 F.2d 1411, 1418 n.16 (Fed. Cir. 1987); *see also LePage's, Inc. v. 3M*, 324 F.3d 141, 152-53 (3d Cir. 2003) (en banc) ("Numerous cases hold that the enforcement of the legal monopoly provided by a patent procured through fraud may violate § 2."). Moreover, while threatened enforcement is likely sufficient to state a claim under *Walker Process*, *see Unitherm Food Sys. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1357-58 (Fed. Cir. 2004), plaintiffs have not alleged any threatened enforcement by AstraZeneca prior to the time the patent litigation was filed. Therefore, plaintiffs have no viable antitrust claim under this theory because it is based on pre-enforcement conduct.

B. <u>No Generic Is Currently Entitled to an 180-Day Exclusivity Period</u>

Plaintiffs' second argument is that they "may still recover for overcharges they must pay for the 180-day period during which, due to Astra's alleged misconduct, all but one generic competitor will be barred from the market." (D.I. 28 at 33.) The fundamental problem with this argument is that there is currently no 180-day period of exclusivity, and there may never be. The 180-day exclusivity period is granted to the first ANDA filer at each dosage level once it receives FDA approval. Here, the first ANDA filers at the 50 mg, 100 mg, and 200 mg dosage levels have

not received FDA approval, and thus there is no 180-day exclusivity period. Sandoz received FDA approval at the 25 mg dosage level after the litigation stay was lifted, but Sandoz is not enjoying the statutory 180-day period of marketing exclusivity for three reasons. First, Sandoz has not begun selling its product. Second, no other ANDA has been approved at the 25 mg dosage level, so once Sandoz begins marketing its product, it will have exclusivity not because of the statutory 180-day period, but because no other generic manufacturer has FDA approval to enter the market. Finally, even if the 25 mg ANDAs are approved in the future, Sandoz has likely forfeited the 180-day period because, as described in the Sandoz approval letter (D.I. 28, Ex. B, at 3), it failed to obtain FDA approval during the 30-month period. Under 21 U.S.C. § 355(j)(5)(B)(iv), this failure results in a forfeiture of the 180-day period. Therefore, because there is no – and may never be – a 180-day period of marketing exclusivity, plaintiffs do not state a claim under this theory.

III. IF THERE IS JURISDICTION FOR THE STATE LAW CLAIMS, THOSE CLAIMS SHOULD BE DISMISSED

According to the Complaint, "This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a)." (D.I. 17 ¶ 14.) In its opening brief, AstraZeneca demonstrated that the Court should decline to exercise supplemental jurisdiction over the state law claims if the federal claim is dismissed. (D.I. 25 at 23-24.) In response, plaintiffs abandon § 1367(a), and now rely only on the Class Action Fairness Act of 2005 ("CAFA").

However, even assuming jurisdiction is proper under CAFA, the state law claims should be dismissed for the same reasons the federal antitrust claim must be dismissed. AstraZeneca cannot

be liable under state law for monopolization (Count II),[5] unfair and deceptive trade practices (Count III),[6] or unjust enrichment (Count IV),[7] because its alleged conduct is not the cause of plaintiffs' alleged injuries.

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[5] The state antitrust laws cited by plaintiffs are to be construed to reach the same conduct covered by the federal antitrust laws. *Wedgewood Inv. Corp. v. Int'l Harvestor Co.*, 613 P.2d 620, 623 (Ariz. Ct. App. 1979); *Partee v. San Diego Chargers Football Co.*, 34 Cal.3d 378, 382 (1983); D.C. Code § 28-4515; *St. Petersburg Yacht Charters, Inc. v. Morgan Yacht, Inc.*, 457 So.2d 1028, 1032 (Fla. 1984); *State v. Gannett Pac. Corp.*, 99 F. Supp. 2d 1241, 1248 (D. Haw. 1999); *Double D Spotting Serv. v. Supervalu, Inc.*, 136 F.3d 554, 561 (8th Cir. 1998); *Orr v. Beamon*, 77 F. Supp. 2d 1208, 1211-12 (D. Kansas 1999), *aff'd*, No. 00-3135, 2001 WL 135439 (10th Cir. Feb. 16, 2001); *Tri-State Rubbish, Inc. v. Waste Mgmt. Inc.*, 998 F.2d 1073, 1081 (1st Cir. 1993); *Commonwealth v. Mass. CRINC*, 392 Mass. 79, 88 (1984); *Michigan Ass'n of Psychotherapy Clinics v. Blue Cross & Blue Shield of Michigan*, 118 Mich. App. 505, 513 (Mich. Ct. App. 1982); *State v. Alpine Air Prods., Inc.*, 490 N.W.2d 888, 894 (Minn. Ct. App. 1992), *aff'd*, 500 N.W.2d 788 (Minn. 1993); Neb. Rev. Stat. § 59-829; *Boulware v. Nevada*, 960 F.2d 793, 800 (9th Cir. 1992); *State v. Ray Bell Oil Co.*, 101 N.M. 368, 370 (N.M. Ct. App. 1984); *Empire Volkswagen, Inc. v. World-Wide Volkswagen Corp.*, 814 F.2d 90, 98 n.4 (2d Cir. 1987); *DKH Corp. v. Rankin-Patterson Oil Co.*, 131 N.C. App. 126, 129 (N.C. Ct. App. 1998); Op. N.D. Att'y Gen., No. 81-35, 1981 WL 156902, at *1 (Apr. 2, 1981) (Ex. C); *Byre v. City of Chamberlain*, 362 N.W.2d 69, 74 (S.D. 1985); *Rockholt Furniture, Inc. v. Kincaid Furniture Co.*, No. 1:96CV00588, 1998 WL 1661384, at *7 (E.D. Tenn. July 6, 1998) (Ex. D), *aff'd*, 188 F.3d (6th Cir. 1999); *Elkins v. Microsoft Corp*., 174 Vt. 328, 336 (2002); *State ex rel. Palumbo v. Graley's Body Shop, Inc.*, 425 S.E.2d 177, 183 (W. Va. 1992); *City of Madison v. Hyland, Hall & Co.*, 243 N.W.2d 422, 428 (Wis. 1976).

[6] Plaintiffs allege that AstraZeneca's conduct caused their injuries under various state unfair competition laws. D.I. 17 ¶¶ 164-165. These claims must be dismissed for the same reasons the plaintiffs have failed to state a claim under federal antitrust laws. *See In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 543 (D.N.J. 2004) (using the standards of federal antitrust standing to evaluate whether plaintiffs state a claim under state consumer protection statutes).

[7] Because AstraZeneca's alleged conduct is not the cause of plaintiffs' injuries, there can be no "unjust" enrichment. There are four additional reasons such a claim cannot succeed. First, because the injunctive relief provisions of the Clayton Act authorize only "forward-looking" remedies, 15 U.S.C. § 26, the grant of retrospective relief such as disgorgement and restitution would contravene the explicit language of the statute, *see FTC v. Mylan Labs, Inc.*, 62 F. Supp. 2d 25, 41 (D.D.C. 1999); *cf. Meghrig v. KFC Western, Inc.*, 516 U.S. 479, 488 (1996) (statute permitting injunctive relief does not authorize claims for restitution). Second, under *Illinois Brick* and its progeny, claims for disgorgement and restitution fail because indirect purchasers such as plaintiffs here lack standing to bring a federal antitrust claim and principles of disgorgement and restitution cannot create indirect purchaser standing in a manner that the antitrust laws forbid. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720, 730-746 (1977); *Mylan*, 62 F. Supp. 2d at 41-42. Third, these claims cannot be brought under federal common law because federal common law cannot nullify the Clayton Act's explicit foreclosure of claims for disgorgement and restitution. *See City of Milwaukee v. Illinois*, 451 U.S. 304, 319 (1981) (no federal common law remedy where federal statutes already address and forbid the purported federal law remedy). Finally, plaintiffs make no reference to state law, much less to the law of any particular state. In the absence of such specificity, it is impossible to determine whether Count IV meets the requirements in any state for an unjust enrichment claim. *See In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1380 (S.D. Fla. 2001); *Washington v. Niagara Mohawk Power Corp.*, 103 F. Supp. 2d 517, 524 (N.D.N.Y. 2000).

IV. IF THE MOTION TO DISMISS IS DENIED, THE COURT SHOULD STAY THIS ACTION

AstraZeneca has also asked this Court to stay the action if it is not dismissed. As AstraZeneca argued in its opening brief, this litigation will be costly and burdensome, which plaintiffs do not, and cannot, dispute. (D.I. 25 at 24-30.) AstraZeneca also demonstrated that a stay would be an appropriate exercise of this Court's discretion under the three-factor test on which this Court relied in *In re Pharmastem Therapeutics, Inc. Patent Litigation*, No. 05-md-1660 GMS (D. Del. Oct. 6, 2005). (D.I. 25 Ex. A.) That test looks to "'(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to a the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set.'" *Id.* at 4 (quoting *Xerox Corp. v. 3 Comm Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999)).

Plaintiffs summarily contend that AstraZeneca has "made no showing concerning its chance of success" on appeal. (D.I. 28 at 39.) In essence, the plaintiffs want the parties to argue the merits of the case in a motion for a stay. But this is exactly backwards. The very purpose of a stay is to postpone the merits argument until the appropriate time. As in *Pharmastem*, the question is whether the outcome of the pending appeal before the Federal Circuit has the potential to narrow or moot the issues in this case. There is no question that it does, and plaintiffs do not seriously contend otherwise.

Therefore, if the Court denies AstraZeneca's motion to dismiss, it should stay the action pending entry of a final decision in the patent litigation.[8] The appeal of the patent case has been fully briefed and only awaits oral argument and a decision.

CONCLUSION

For the reasons set forth above and in its opening brief, AstraZeneca respectfully requests that this Court enter an order dismissing plaintiffs' Complaint or, if the motion to dismiss is denied, an order staying all proceedings in this action, including any motions, pleadings, and discovery, pending the entry of a final decision in the patent litigation.

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October 10, 2006

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[8] Plaintiffs ask the Court to permit them to obtain the discovery produced in the underlying patent case if the stay motion is granted. (D.I. 28 at 37.) Because the outcome of the case before the Federal Circuit may dispose of all the issues in this case, no discovery should be permitted if a stay is ordered.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on October 10, 2006 I electronically filed the foregoing with the Clerk of the Court using CM/ECF which will send notification of such filing to Gary F. Taynor and A. Zachary Naylor.

I further certify that on October 10, 2006 I caused that copies of the foregoing be served on the following counsel in the manner indicated:

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EXHIBIT A

Drugs@FDA
Glossary of Terms

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Abbreviated New Drug Application (ANDA)

An Abbreviated New Drug Application (ANDA) contains data that, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the innovator drug). Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

Abbreviated New Drug Application (ANDA) Number

This six digit number is assigned by FDA staff to each application for approval to market a generic drug in the United States.

Active Ingredient

An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Approval History

The approval history is a chronological list of all FDA actions involving one drug product having a particular FDA Application number (NDA). There are over 50 kinds of approval actions including changes in the labeling, a new route of administration, and a new patient population for a drug product.

Application

See New Drug Application (NDA), Abbreviated New Drug Application ANDA), or Biologic License Application (BLA)

Approval Letter

An official communication from FDA to a new drug application (NDA) sponsor that allows the commercial marketing of the product.

Application Number

See FDA Application Number

Biologic License Application (BLA)

Biological products are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires a firm who manufactures a biologic for sale in interstate commerce to hold a license for the product. A biologics license application is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical affects of the biologic product. If the information provided meets FDA requirements, the application is approved and a license is issued allowing the firm to market the product.

Biologic Product

A biologic product is any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries. Biologic products are a subset of "drug products" distinguished by their manufacturing processes (biological process vs. chemical process). In general, the term "drugs" includes biologic products.

Brand Name Drug

A brand name drug is a drug marketed under a proprietary, trademark-protected name.

Company

The company (also called applicant or sponsor) submits an application to FDA for approval to market a drug product in the United States.

Discontinued Drug

A discontinued drug is a drug product that has been removed from the market in the United States for reasons other than safety or effectiveness.

Dosage Form

A dosage form is the physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable.

Drug

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of of a medicine but not a device or a component, part or accessory of a device.
- Biologic products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process vs. biological process.)

Drug Product

The finished dosage form that contains a drug substance, generally, but not necessarily in association with other active or inactive ingredients.

FDA Action Date

The action date tells when any FDA regulatory action, such as an original or supplemental approval took place.

FDA Application Number

This number, also known as the NDA (New Drug Application) number, is assigned by FDA staff to each application for approval to market a new drug in the United States. One drug can have more than one application number if it has different dosage forms or routes of administration

Generic Drug

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug

product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.

Label

The FDA approved label is the official description of a drug product which includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children, and other populations; and safety information for the patient. Labels are often found inside drug product packaging.

Marketing Status

Marketing status indicates how a drug product is sold in the United States. Drug products in Drugs@FDA are identified as:

- Prescription
- Over-the-counter
- Discontinued - Drug products that have been removed from the market for reasons other than safety or effectiveness
- None - Drug products that have been tentatively approved

Medication Guide

A medication guide contains information for patients' understanding of how to safely use a drug product.

NDA (see New Drug Application)

New Drug Application (NDA)

When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States. For internal tracking purposes, all NDA's are assigned an NDA number.

New Drug Application (NDA) Number

This six digit number is assigned by FDA staff to each application for approval to market a new drug in the United States. A drug can have more than one application number if it has different dosage forms or routes of administration. In Drugs@FDA, you can find the NDA number under the column named "FDA Application."

Over-the-Counter Drugs (OTC)

FDA defines OTC drugs as safe and effective for use by the general public without a doctor's prescription.

Patient Package Insert (PPI)

A patient package insert contains information for patients' understanding of how to safely use a drug product.

Pharmaceutical Equivalents

FDA considers drug products to be pharmaceutical equivalents if they meet these three criteria:

- they contain the same active ingredient(s),
- they are of the same dosage form and route of administration
- they are identical in strength or concentration

Pharmaceutically equivalent drug products may differ in characteristics such as

- shape
- release mechanism
- labeling (to some extent)
- scoring
- excipients (including colors, flavors, preservatives)

Prescription Drug Product

A prescription drug product requires a doctor's authorization to purchase.

Product Number

A product number is assigned to each drug product associated with an NDA (New Drug Application). If a drug product is available in multiple strengths, there are multiple product numbers.

Reference Listed Drug (see RLD)

Review

A review is the basis of FDA's decision to approve an application. It is a comprehensive analysis of clinical trial data and other information prepared by FDA drug application reviewers. A review is divided into sections on medical analysis, chemistry, clinical pharmacology, biopharmaceutics, pharmacology, statistics, and microbiology.

RLD (Reference Listed Drug)

A Reference Listed Drug is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart.

Route

A route of administration is a way of administering a drug to a site in a patient. A comprehensive list of specific routes of administration appears in the CDER Data Standards Manual.

Strength

The strength of a drug product tells how much of the active ingredient is present in each dosage.

Supplement

A supplement is an application to allow a company to make changes in a product that already has an approved new drug application (NDA). CDER must approve all important NDA changes (in packaging or ingredients, for instance) to ensure the conditions originally set for the product are still met.

Supplement Number

A supplement number is associated with an existing FDA New Drug Application (NDA) number. Companies are allowed to make changes to drugs or their labels after they have been approved. To change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug, a company must submit a supplemental new drug application (sNDA). Each sNDA is assigned a number which is usually, but not always, sequential, starting with 001.

Supplement Type

Companies are allowed to make changes to drugs or their labels after they have been

approved. To change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug, a company must submit a supplemental new drug application (sNDA). The supplement type refers to the kind of change that was approved by FDA. This includes changes in manufacturing, patient population, and formulation.

Tentative Approval

If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product.

Therapeutic Equivalence (TE)

Drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product. Drug products are considered to be therapeutically equivalent **only** if they meet these criteria:

- they are pharmaceutical equivalents (contain the same active ingredient(s); dosage form and route of administration; and strength.)
- they are assigned by FDA the same therapeutic equivalence codes starting with the letter "A ." To receive a letter "A", FDA
  - designates a brand name drug or a generic drug to be the Reference Listed Drug (RLD).
  - assigns therapeutic equivalence codes based on data that a drug sponsor submits in an ANDA to scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the Reference Listed Drug).

Therapeutic Equivalence (TE) Codes

The coding system for therapeutic equivalence evaluations allows users to determine whether FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products (first letter) and to provide additional information on the basis of FDA's evaluations (second letter). Sample TE codes: AA, AB, BC (More on TE Codes)

- FDA assigns therapeutic equivalence codes to pharmaceutical equivalent drug products. A drug product is deemed to be therapeutically equivalent (**"A"** rated) only if
  - a drug company's approved application contains adequate scientific evidence establishing through *in vivo* and/or *in vitro* studies the bioequivalence of the product to a selected reference listed drug.
  - those active ingredients or dosage forms for which no *in vivo* bioequivalence issue is known or suspected.
- Some drug products may have more than one TE Code. (More about multiple TE Codes)
- Those products which the FDA does not deem to be therapeutically equivalent are **"B"** rated. (More on TE Codes)

Over-the-counter drugs are not assigned TE codes

FDA/Center for Drug Evaluation and Research
Division of Library and Information Services
Page Last Updated: September 10, 2004

EXHIBIT B

United States Department of Health & Human Services

Testimony

Statement by
Gary Buehler, R.Ph.
Director of the Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services

on
Improving Access to Generic Drugs

before
Special Committee on Aging
United States Senate

Thursday, July 20, 2006

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Gary Buehler, R.Ph, Director of the Office of Generic Drugs (OGD), in the Center for Drug Evaluation and Research (CDER), at the U.S. Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to testify about FDA's efforts to expedite the approval of generic drug products.

FDA understands that Congress and the public are concerned about the high cost of prescription drugs. Generic drugs play an important role in granting access to affordable products that will benefit the health of consumers, especially seniors - who often are on a fixed income. Prompt approval of generic drug product applications, also known as abbreviated new drug applications (ANDA), is imperative to making generic products available to American consumers at the earliest possible date.

Statutory Provisions

Prior to the passage of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Amendments) of 1984, FDA's primary statute, the Federal Food, Drug, and Cosmetic (FD&C) Act, did not provide for the approval of generic drugs. The Hatch-Waxman Amendments established the ANDA approval process, which permits FDA to approve generic versions of previously approved innovator drugs without the submission of clinical studies and other kinds of data that are required in a full new drug application (NDA). An ANDA refers to the previously approved NDA of the innovator drug and relies upon the Agency's finding of safety and effectiveness for that drug. Also, with respect to each unexpired patent submitted to FDA by the owner of the innovator drug and published by FDA in the Orange Book[1], an ANDA contains a certification that the ANDA applicant either will wait for the patent to expire before marketing the drug or that the applicant challenges the patent as invalid or not infringed.

The Hatch-Waxman Amendments have been very successful and have provided for the approval of over 8,000 generic drug products. These products are lower cost, high quality products that have saved the American public and the government billions of dollars.

FDA has taken a number of significant steps to provide greater access to affordable prescription medications, including unprecedented steps to lower drug costs by helping to speed the

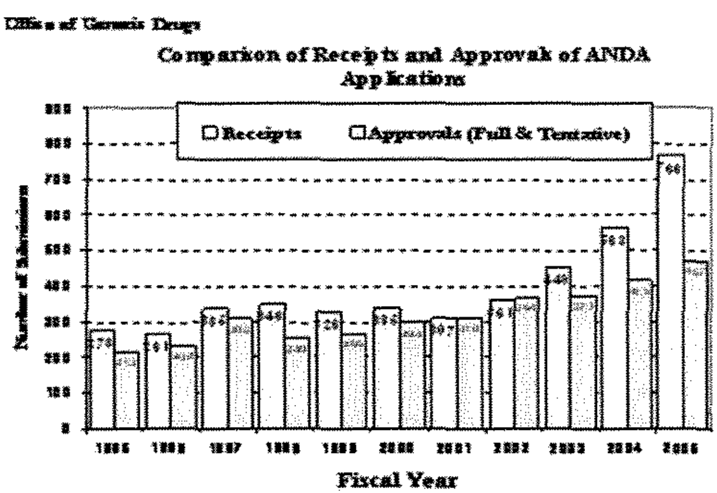
development and approval of low-cost generic drugs after legitimate patents have expired on branded drugs. Generic drugs typically cost 50 to 70 percent less than their brand-name counterparts. In 2003, FDA published a final rule to improve access to generic drugs and lower prescription drug costs for millions of Americans. This rule was first proposed in response, in part, to Federal Trade Commission recommendations and other changes the Agency identified as being useful in improving generic competition. The rule limits an innovator drug company to only one 30-month stay of a generic drug applicant's entry into the market for resolution of a patent challenge. These changes will save Americans over $35 billion in drug costs over the next 10 years, and will also provide billions in savings for the Medicare and Medicaid programs. We were pleased that elements of this rule were codified as part of the Medicare law and that, with FDA's technical assistance, the law added additional mechanisms to enhance generic competition in the marketplace.

In addition, since FY2001, the Administration and Congress have increased funding for FDA's generic drug program by 66 percent, a clear sign of the important role played by OGD. These increases have enabled FDA to hire additional expert staff to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. While there remains work to be done, as I will discuss, we have been able to produce significant reductions in approval times for generic drugs since 2002 that consequently will save consumers billions by generally reducing the time for developing generic drugs and making them available.

The Office of Generic Drugs' Workload
Much concern has been raised from the public and Congress about a "backlog" of pending ANDAs, currently under OGD review. FDA has received an increased number of ANDAs in the last few years. OGD generally maintains a "first-in, first-reviewed" policy for ANDAs. FDA instituted this generic drug review priority to ensure the integrity of the approval process. A number of factors govern the timing of generic drug approvals, including: whether the application is of high quality, meets inspection standards and the scientific and technical requirements for approval, and whether patent protection and exclusivity periods have expired on the innovator drug.

There are several contributing causes to the increased number of generic applications FDA is receiving. Among these are the approvals of many new innovator drugs in the 1990s with patents that are now expiring, as well as the burgeoning number of new generic firms entering the market. Over the last five years, the number of applications submitted to OGD has increased by 150 percent. In fiscal year (FY) 2001, OGD received 307 ANDAs. In FY 2002 submissions increased 17.6 percent to 361. In FY 2003, they increased 24.3 percent to 449. In FY 2004, they increased 25.3 percent to 563. And, in FY 2005, they increased 36 percent to 766 applications submitted for review (see figure 1). Just last month, June 2006, we approved (or tentatively approved, meaning an application is technically ready for approval, but patent or exclusivity prevents immediate approval) 45 applications, however, the number of pending applications grew substantially because we received 92 applications. Clearly, this rate of increase in applications results in a dramatic increase in the workload for the review staff in OGD.

Figure 1



Although OGD still has a backlog, figure 1 also demonstrates that we have managed to increase the number of approvals each year. In FY 2001, OGD approved (or tentatively approved) 310

ANDAs and increased the annual number of approvals to 467 (or tentative approvals) in FY 2005. OGD's efforts are also evident when looking at the median approval time. The median approval times have decreased from 18.4 months in FY 2001 to 16.3 months in FY 2005. In FY 2003, OGD approved (or tentatively approved) 132 applications in less than 15 months after receipt. In FY 2004, that number increased to 146 in less than 15 months and increased further to 174 in FY 2005 (102 of which were approved in less than 12 months). Despite these challenges, FDA has managed to maintain its rate of approval of more than one generic drug application a day.

It is important to understand that a pending ANDA has not been reviewed. When a pending ANDA is initially reviewed and deficiencies are communicated to the company, the application is no longer considered pending. However, when the company submits an amendment to its ANDA to address the identified deficiencies, the application is again considered pending. Therefore, the ANDAs in the backlog are not all unreviewed, but may be applications that have had an initial review and are now awaiting a second or subsequent review of the company's attempts to satisfy approval requirements.

FDA has taken significant steps to improve our resources. Total spending on the Generic Drug Program is $64.6 million, which is more than a 66 percent increase from the comparable FY 2001 amount. FDA has increased its generic drugs full-time equivalent (FTE) positions from 134 in FY 2001 to 201 in FY 2006. Last year, FDA added 12 new FTE positions to OGD's staff. These individuals, now fully trained, have recently reached the point in their learning curve where they are now full contributors to the efforts of OGD. In addition, OGD has taken actions to streamline the ANDA review process. These actions include adding a third chemistry review division and a fifth team in OGD's Division of Bioequivalence. Also, a number of new review practices have been implemented to improve interactions with generic drug companies. We have begun utilizing non-reviewer Project Management staff to take certain actions not requiring scientific expertise, thus alleviating the burden of these activities on the review staff. OGD has instituted other efficiencies to application review. These include:

- reviewing Drug Master Files (DMFs) prior to the time the related ANDAs are assigned, because the DMF evaluation is often the limiting factor in completing the ANDA review; (Experience with expedited review in the President's Emergency Plan for AIDS Relief program has shown that early DMF review generally shortens overall time to approval.)
- relying upon telephone discussions with ANDA sponsors when appropriate, as opposed to written correspondence, to resolve deficiencies more efficiently and expeditiously early in the review process;
- assigning applications to reviewers with relevant expertise or experience with a particular drug class to enable more efficient and timely reviews; and
- utilizing a new review format for the chemistry review. It is based on the structure of applications in the International Conference on Harmonization Common Technical Document. This format also is in keeping with CDER's quality-by-design initiatives and should eventually decrease review times and the need for submission of some supplements to approved ANDAs.

Because of these efforts, on the very day that the last patents or exclusivities expire on the innovator product, OGD has been able to approve at least one generic drug application in most cases. And, if there are no products eligible for 180-day exclusivity, we have usually been able to approve two or more applications for the same products. In fact, very recently, FDA approved generic applications for pravastatin (Pravachol), sertraline (Zoloft), and simvastatin (Zocor) when the innovator protections expired. Many Americans use one of these drugs. The availability of generic versions of these three drugs should produce savings measured in the billions of dollars per year. We will work to continue our success so far in staying ahead of the curve on first-time generics and responding to pending applications.

Citizen Petitions
FDA regulations permit any interested person to file a citizen petition requesting FDA "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action" (Title 21, *Code of Federal Regulations* 10.25 and 10.30). Citizen petitions may be submitted at any time, requesting that FDA impose new criteria for approval of ANDAs. The petitions often make serious challenges to whether or not a generic product can be approved; that is, whether a specific application or a group of applications would meet the statutory requirements for approval.

It is incumbent upon FDA to consider and address the merits of petitions. The data and information submitted with these petitions require detailed analysis and precise scientific documentation, often involving multiple disciplines within CDER. Because the same issues sometimes are raised in a subsequent court challenge to an ANDA approval and because petitioners sometimes submit non-scientific petitions that raise purely legal questions related to ANDA approvals, a thorough legal review is also necessary. Although it is not required that a citizen petition response be issued before approval of a related ANDA, it is important that FDA comprehensively assess the scientific issues prior to approval of the ANDA. It is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions.

A high percentage of the petitions OGD reviews are denied. An analysis of petitions answered between calendar years 2001 and 2005, raising issues about the approvability of generic products (42 total responses), showed that FDA denied 33, denied three in part, and granted six. It should be noted that when petitions are granted, wholly or in part, it is often because FDA already has the proposed scientific or legal standard in place or is already planning to take the action that the petition requests. While the citizen petition process is a valuable mechanism for the Agency to receive information from the public, it is noteworthy that very few of these petitions on generic drug matters have presented data or analysis that significantly altered FDA's policies. Of the 42 citizen petition responses examined, only three petitions led to a change in Agency policy on the basis of data or information submitted in the petition.

CDER has made considerable efforts in the last year-and-a-half to improve the process for responding to citizen petitions. As part of this process, OGD constituted a group of highly qualified and skilled scientists dedicated to assessing the citizen petitions related to generic drugs and formulating FDA's responses to them. Other improvements include: increased prospective management of the petition response process; development of clear timelines for completing actions; and improved communication among the CDER components involved in responding to citizen petitions.

Authorized Generics

The term "authorized generic" is generally used to describe an instance when an innovator company, in the face of pending generic competition, repackages its own product and markets it as a "generic." Prior FDA approval is not needed for the innovator company to do this, as review and approval occur under the auspices of the innovator's approved NDA. Generic drug companies, through citizen petitions and lawsuits, have sought FDA's intervention to halt the marketing of authorized generics. FDA determined, and the courts upheld, that the FD&C Act does not give FDA authority to intervene in the matter.

CONCLUSION

FDA appreciates the Committee's interest and concern about expediting the approval of generic drug products and the opportunity to discuss these important issues. I am constantly impressed by the dedication, skills and effectiveness of FDA staff responsible for reviewing generic drugs. In spite of a tremendous workload, be assured that there is a sense of purpose and knowledge, among my staff and this Administration that they are working towards an important public health mission. FDA will continue to work towards greater efficiency in ANDA review and attempt to deal with the issues discussed today and the many emerging challenges ahead. We are committed to continue to make additional generic products available to the American public as soon as legally possible. I would be pleased to respond to questions.

Footnotes:

[1]The publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness.

EXHIBIT C

1981 WL 156902 (N.D.A.G.)

(Cite as: 1981 WL 156902 (N.D.A.G.))

Office of the Attorney General
State of North Dakota

***1** Opinion No. 81-35
Date Issued: April 2, 1981

James M. Vukelic
Hettinger County State's Attorney

--QUESTION PRESENTED--

Whether promulgation of minimum settlement damages and fees guidelines by a surface owners association, for oil exploration and development activities would violate state antitrust law.

--ATTORNEY GENERAL'S OPINION--

It is my opinion that promulgation of such guidelines would violate the state's antitrust law as found in Chapter 51-08 of the North Dakota Century Code.

--ANALYSIS--

Section 51-08-01, N.D.C.C., reads:

51-08-01. POOLS AND TRUSTS PROHIBITED. It shall be unlawful for any corporation organized under the laws of this state or doing business in this state, or any partnership, association, or individual, to create, enter into, or become a member of, or a party to, any pool, trust, agreement, contract, combination, or confederation, to regulate or fix the price of any article of merchandise, commodity, or property, or to fix or limit the amount or quantity of any article, property, merchandise, or commodity to be manufactured, mined, produced, exchanged, or sold in this state.

There is no North Dakota case law decided under this statute. The statute is, however, similar to the Sherman Antitrust Act, 15 U.S.C. §§ 1-7 (1977). Drawing from the body of knowledge developed in the federal system provides instruction as to what courses of action are permissible, and what courses of action are prohibited.

The federal law states that contracts, combinations, and conspiracies in restraint of trade are illegal. This law has been judicially refined to mean that only unreasonable restraints of trade are unlawful. Standard Oil Co. v. U.S., 211 U.S. 1 (1911). A 'rule of reason' test was developed.

1981 WL 156902 (N.D.A.G.)

(Cite as: 1981 WL 156902 (N.D.A.G.))

Even in the face of this 'rule of reason,' some activities were deemed so anticompetitive as to constitute per se violations of the law. These per se activities need not be subjected to the analysis of reasonableness. Price fixing is one such per se activity. Northern Pacific Railway Co. v. U.S., 356 U.S. 1 (1958).

Section 51-08-01, N.D.C.C., likewise specifically lists price fixing as a prohibited activity. This statutory language and the developed body of federal law clearly points to the conclusion that price fixing is anticompetitive and a violation of the anti-trust laws of the state. Therefore, the actions of pooling efforts and fixing a price is an apparent violation of the state law.

Owners of the surface and mineral estates have the right of fee owners of realty to determine who may enter onto their property, and what activities may be conducted thereon. Individually, each owner may enter into any agreement with licensees upon the land for fixing damages and defining the scope of activities to be conducted. These agreements can be characterized as a sale or exchange of a license from the owner of the land to the licensee.

A somewhat analogous relationship exists in the area of patent law. The holder of a patent has exclusive right, by law, to determine who may make use of a patent during the patent period. The consenting of a patent holder to another to make use of the patent has been held to be a license. General Motors Corporation v. Dailey, 93 F.2d 938 (6th Cir., 1937).

***2** Just as the landholder may exercise complete monopoly control over the property owned, so too has the patent holder the individual right to enjoy a monopoly on the patent owned.

Although it is legal for the individual patent holder to fix any price for a patent, it is a per se violation of Section 1 of the Sherman Act for two or more patent holders to combine their patents and authorize a fixed price for the use of their patents. U.S. v. Line Material Co., et al., 333 U.S. 287 (1948).

If it is unlawful per se for two or more patent holders to combine together and fix prices on the licensing of their patents, by analogy, it is reasonable to conclude that two or more fee owners of realty cannot combine and fix prices on the licensing of the use of their real property. To do so would amount to a combination to fix the prices of property, and as such is a violation of the state's Antitrust Law.

--EFFECT--

This opinion is issued pursuant to Section 54-12-01, N.D.C.C. It governs the actions of public officials until such time as the question presented is decided by the courts.

Robert O. Wefald

1981 WL 156902 (N.D.A.G.)

(Cite as: 1981 WL 156902 (N.D.A.G.))

Attorney General

Prepared by:

Gary H. Lee

Assistant Attorney General

1981 WL 156902 (N.D.A.G.)

END OF DOCUMENT

EXHIBIT D

H
Briefs and Other Related Documents
Rockholt Furniture v. Kincaid Furniture Co.E.D.Tenn.,1998.Only the Westlaw citation is currently available.

United States District Court, E.D. Tennessee.
ROCKHOLT FURNITURE, INC., Plaintiff,
v.
KINCAID FURNITURE COMPANY, INC. and Rhodes Furniture Company, Defendants.
No. 1:96CV00588.

July 6, 1998.

MEMORANDUM

COLLIER, J.
***1** Before the Court are Defendants Kincaid Furniture Company, Inc.'s ("Kincaid") and Rhodes Furniture Company's ("Rhodes") Motions for Summary Judgment (Court File Nos. 28 and 31). Plaintiff Rockholt Furniture, Inc. ("Rockholt") responded (Court File No. 37) and Kincaid and Rhodes replied (Court File Nos. 40 and 41). For the following reasons, the Court will GRANT Kincaid's and Rhodes's motions. There being no other issues, the Court will ORDER the case DISMISSED.

I. *RELEVANT FACTS*

Kincaid manufactures solid wood furniture. Kincaid sells this furniture to retail establishments throughout the country. Some of the retailers Kincaid sells to maintain a special independent dealer arrangement known as a Kincaid gallery. In a Kincaid gallery, the retailer divides the store's showroom into room-like sections to display the furniture as if it were arranged in a home. It was Kincaid's experience that a gallery type display yielded two and a half to three times the volume yielded by an independent dealer not maintained as a gallery (Dennis Kincaid Deposition, p. 30, Supplemental File to Court File No. 29).

From 1985 until May 1996, Rockholt purchased furniture from Kincaid and sold that furniture at its Decatur, Tennessee store. Rockholt did not maintain a Kincaid gallery. Rockholt contends there was a verbal contract between it and Kincaid for Rockholt to remain a dealer of Kincaid products as long as Rockholt paid for the furniture it ordered (Rockholt's Response to the Motions for Summary Judgment, p. 2, Court File No. 37). Calvin Rockholt, owner of the Rockholt store, testified as follows regarding the contract:

Q: Well, taking that it may or may not be in their best interest, if they felt it was in their best interest to have Rockholt Furniture and you didn't want to carry their line, you don't have any kind of written agreement or any kind of understand that you're going to continue handling it; is that correct?
A: That's correct.
Q: And is it your understanding that that's the typical arrangement between-you're talking about the typical arrangement between a dealer and furniture supplier in the industry, that is, generally, if the dealer, for whatever reason that is acceptable to him, decides it's not in his best interest to carry a line, he can just not order any more furniture from that manufacturer; is that correct?
A: Yes.

....Q: Is the understanding that you consider that you had with Kincaid that you described the same with all of the manufacturers that you carry in your store, that is, you have a partnership arrangement?
A: Yes.
Q: And as long as you are doing your end of the bargain, then they should continue selling to you indefinitely?
A: Yes.
Q: Have you ever had anyone ask you to sign a contract or request that you sign a contract?
A: No.

(Calvin Rockholt Deposition, pp. 29-30, Supplemental File to Court File No. 29, Exh. D (" Depo Excerpts I")).

***2** In a later portion of his deposition, Calvin Rockholt again testified about the contract between Kincaid and Rockholt:
Q: Can you tell me if you have any comment in this letter [FN1] regarding your contract with Kincaid or your agreement with Kincaid?

FN1. The parties are referring to a letter Calvin Rockholt sent to Steve Kincaid, president of Kincaid, after Mr. Rockholt learned Kincaid was not going to continue to sell furniture to Rockholt.

A: The only thing would be where Dennis-where I say in the second paragraph ten years ago Dennis called on me to put Kincaid into our store. At that time Dennis was trying to sell us the Kincaid product and I bought it at that time. A verbal agreement to buy the product. Dennis approached me about putting it in the most prominent part of the store, and we did that. It had the best area of our store with the best lighting and the best display area that we had at that time. And I fulfilled that agreement with Dennis.
Q: But you didn't feel the need to call to Mr. Steve Kincaid's attention anything about a contract or agreement in that letter; is that correct?
A: Well, there was not a written contract. That was what I was referring to in the second paragraph when I said ten years ago when Dennis called on me. And I go on to refer to things that I did.

(Calvin Rockholt Deposition, pp. 74-75, Court File No. 37, Exh. A ("Depo. Excerpts II")). Mr. Rockholt's best description of the contract was, "It was always just terminology, even within the industry, if you pay your bills and do a decent job of representing the product, people would continue to sell to you" (Calvin Rockholt Depo. Excerpts I, p. 56; *See also id.* at p. 57).

In November 1993, Rhodes opened a retail furniture store in Chattanooga, Tennessee. Rhodes's store was located approximately 40 to 50 miles from the Rockholt store and also sold Kincaid furniture. Rhodes was Kincaid's largest customer and the Chattanooga store maintained a Kincaid gallery.

In March of 1994, Stan Lowenstein, manager of Rhodes's Chattanooga store, complained to Robert Lemons, National Accounts Representative for Kincaid, about a customer who had visited the Rhodes store. The customer asked Rhodes to beat a price offered by Rockholt on a certain piece of Kincaid furniture. Rhodes offered to beat the price by $100, but the customer did not purchase the item. Instead, she returned to the Rockholt store seeking an even better deal. Rhodes refused to make another offer to the customer (*See* D. Kincaid Depo., pp. 34-35, Supplemental File to Court File No. 29, Exh. C; Exhibit 4 to Robert A. Lemons Deposition, Court File No. 37, Exh. E ("Lemons Depo. Excerpts I")).

The essence of Lowenstein's complaint was he believed Rockholt maintained only a limited inventory of Kincaid furniture. Lowenstein believed when a Rockholt customer wanted to view items not carried by Rockholt, Rockholt sent those customers to Rhodes. Once the customer located the items they wanted at Rhodes, Rockholt then special ordered the furniture for the customers. Rhodes felt this practice, if true, permitted Rockholt to receive the benefit of Rhodes's large inventory and gallery display without the costs associated with maintaining such a large display (*See* Stan Lowenstein Affidavit, ¶ 4, Supplemental File to Court File No. 29, Exh. E).

***3** Lemons instructed Dennis Kincaid, Kincaid's marketing representative for the area, to investigate Lowenstein's complaint (D. Kincaid Depo., p. 35). Dennis Kincaid spoke with both Calvin Rockholt and Stan Lowenstein about the customer shopping incident. After Dennis Kincaid's conversation with Lowenstein, he faxed the following synopsis of the conversation to Lemons:
I called Stan to express support and concern about competitive discounting, etc. He was respectable but harsh and not receptive to my review of the shopping incident. He told me his version and indicated that Rockholt had lied to me, says Rockholt habitually sends customers to shop his store on all shared lines, indicating he will special order and beat prices.

Rhodes made the sale in question at 28% margin. Stan feels that competitors should not have access to anything he carries unless they are an AUTH. "K" gallery [authorized Kincaid gallery].
He did not believe my report on Rockholt display, stocking of Kincaid. He agreed to send shoppers to Rockholt to verify pricing, display, etc.
He confirmed that Rockholt advertising was institutional-no product identity.
He has no problem with Rockholt's access to line as long as they don't drastically cut prices. I will try to influence Rockholt not to do so.

(Exhibit 5 to Lemons Depo. Excerpts I)

With respect to the relationship between Rockholt, Kincaid, and Rhodes, Calvin Rockholt also testified, "After Rhodes entered the Chattanooga market, Dennis Kincaid pressured Rockholt to establish a 42% profit margin. According to Dennis Kincaid, this was the margin Rhodes and Kincaid desired that we establish. This pressure to establish a specific profit margin came from Dennis Kincaid and it continued from the time that Rhodes entered the Chattanooga market until Rockholt was terminated as a distributor of Kincaid products" (Calvin Rockholt Affidavit, ¶¶ 6-7, Court File No. 39).[FN2]

FN2. Calvin Rockholt's deposition testimony did not indicate Rhodes also desired Rockholt to set it prices at a 42% profit margin (Calvin Rockholt Depo. Excerpts II, pp. 34-35). Furthermore, while Mr. Rockholt's testimony regarding his conversation with Dennis Kincaid *could possibly* be admissible against Kincaid as an admission by a party opponent, this evidence is likely inadmissible hearsay with respect to Rhodes. However, as discussed in Section III(A) of this Memorandum, even if the Court accepts this evidence, there is insufficient proof of a violation of Section 1 of the Sherman Act.

Kincaid also sold its furniture to another area store, Morgan Furniture. Prior to 1992, Morgan Furniture maintained stores in Morristown and Dayton, Tennessee. Since the Dayton, Tennessee store was only eleven miles from Rockholt's store, Kincaid initially protected Rockholt's distribution area by permitting Morgan Furniture to only sell Kincaid products at its Morristown store (D. Kincaid Depo., pp. 99-100). However, in 1992 or 1993, Morgan Furniture closed it Morristown store and asked to sell Kincaid furniture in its Dayton store.

Kincaid discussed Morgan Furniture's request with Rockholt who had no objection. The Tennessee River separated Morgan Furniture from Rockholt and the only mode of transportation between the stores was by ferry. This was thought to be an effective competition deterrent and Kincaid permitted Morgan Furniture to sell Kincaid products in its Dayton store (*Id.* at 100).

In February of 1996, Morgan Furniture became a Kincaid gallery and began to display Kincaid products in a home like arrangement (Robert A. Lemons Deposition, p. 17, Supplemental File to Court File No. 29, Exh. F ("Lemons Depo. Excerpts II")). That same year, the State of Tennessee also began to build a bridge across the Tennessee River. This meant customers would have easier access to both the Rockholt and Morgan Furniture stores (*Id.* at 59-60).

*4 On May 14, 1996, Kincaid sent Rockholt a letter terminating Kincaid's relationship with Rockholt. The letter stated:
We have determined that we can best increase the sale of Kincaid products in your area through fewer dealers, therefore, this is notification from this date forward, we will not accept any new orders for stock merchandise....
Thank you for the orders which you have sent us in the past. If our market plans or philosophy changes in the future, we hope that we may be able to renew our relationship.

(Exhibit 2 to Calvin Rockholt Depo. Excerpts II).

Calvin Rockholt also had a discussion with Dennis Kincaid about the termination of the relationship between Rockholt and Kincaid. In his affidavit, Calvin Rockholt described this conversation as

follows:

At the time Dennis Kincaid informed me of Kincaid's decision to terminate Rockholt as a distributor of Kincaid products, he did not mention either the construction of a new bridge between Dayton and Decatur or the establishment of Morgan Furniture as a Kincaid gallery as a factor in Kincaid's decision.

During this conversation, Dennis Kincaid told me that our termination was as a result of Kincaid's agreement with Rhodes to terminate me. He told me that the decision "ain't right," that Kincaid was showing "great disloyalty" to Rockholt, and that Rhodes finally got me because I would not raise my prices to the level requested by Rhodes and Kincaid.

Dennis Kincaid also told me that his superiors could not give him much information on why Rockholt was being terminated, but that he thought that it was a "shitty decision," and "it was a shame to take a line work your ass off and build it up for ten years just to have it taken away from you."

(Calvin Rockholt aff., ¶¶ 8-10).

On December 6, 1996, Rockholt filed suit against Kincaid and Rhodes alleging violations of the Sherman Act, 15 U.S.C. § 1; and Tennessee State Antitrust law, *Tenn.Code Ann.* §§ 47-25-101 and -102; and for claims for breach of contract; unlawful inducement of breach of contract, *Tenn.Code Ann.* 47-50-109; tortious interference with a prospective business advantage; and conspiracy.FN3 Kincaid's and Rhodes's Motions for Summary Judgment challenge Rockholt's proof on all of these claims. The motions are now ripe for the Court's adjudication.

FN3. Rockholt did not assert some of these claims until its amended complaint filed on May 8, 1997 (Court File No. 16).

II. *STANDARD OF REVIEW*

Under *Fed.R.Civ.P.* 56(c), the Court will render summary judgment if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. The burden is on the moving party to conclusively show no genuine issue of material fact exists, *Lansing Dairy, Inc. v. Espy,* 39 F.3d 1339, 1347 (6th Cir.1994); *Kentucky Div., Horsemen's Benev. & Prot. Assoc., Inc. v. Turfway Park Racing Assoc., Inc.,* 20 F.3d 1406, 1411 (6th Cir.1994), and the Court must view the facts and all inferences drawn therefrom in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587 (1986); *Oakland Gin Co., Inc. v. Marlow,* 44 F.3d 426, 429 (6th Cir.1995); *City Management Corp. v. U.S. Chemical Co., Inc.,* 43 F.3d 244, 250 (6th Cir.1994).

***5** Once the moving party presents evidence sufficient to support a motion under Rule 56, the nonmoving party is not entitled to a trial merely on the basis of allegations. The nonmoving party may not rest on its pleadings, but must come forward with some significant probative evidence to support its claim. *Celotex Corp. v. Catrett,* 477 U.S. 317, 324 (1986); *Lansing Dairy,* 39 F.3d at 1347; *Horsemen's Benev.,* 20 F.3d at 1411; *see also Guarino v. Brookfield Township Trustees,* 980 F.2d 399, 404-06 (6th Cir.1992) (holding courts do not have the responsibility to search *sua sponte* the record for genuine issues of material fact). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to summary judgment. *Celotex,* 477 U.S. at 323.

The Court determines whether sufficient evidence has been presented to make the issue of fact a proper jury question, but does not weigh the evidence, judge the credibility of witnesses, or determine the truth of the matter. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 249 (1986); *60 Ivy Street Corp. v. Alexander,* 822 F.2d 1432, 1435-36 (6th Cir.1987). The standard for summary judgment mirrors the standard for directed verdict. The Court must decide "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson,* 477 U.S. at 251-52. There must be some probative evidence from which the jury could reasonably find for the nonmoving party. If the Court concludes a fair-minded jury could not return

a verdict in favor of the nonmoving party based on the evidence presented, it may enter a summary judgment. *Id.; Lansing Dairy,* 39 F.3d at 1347; *Horsemen's Benev.,* 20 F.3d at 1411.

III. *DISCUSSION*

The Court will address in turn each of Rockholt's claims.

A. Sherman Act, 15 U.S.C. § 1

"Section 1 of the Sherman Act requires that there be a 'contract, combination ... or conspiracy' between the manufacturer and other distributors in order to establish a violation." *Monsanto Co. v. Spray-Rite Service Corp.,* 465 U.S. 752, 760 (1984). All parties agree the Supreme Court's analysis in *Monsanto* controls this Court's decision regarding whether there is sufficient evidence of a Sherman Act violation.

In *Monsanto,* the Supreme Court explained there are two important distinctions at the center of every di stributor-termination case under Section 1 of the Sherman Act. *Id.* at 760-761. "First, there is the basic distinction between concerted and independent action.... Independent action is not proscribed." *Id.* at 761. "The second important distinction in distributor-termination cases is that between concerted action to set prices and concerted action on nonprice restrictions. The former hav[ing] been *per se* illegal since the early years of national antitrust enforcement. The latter [being] judged under the rule of reason, which requires a weighing of the relevant circumstances of a case to decide whether a restrictive practice constitutes an unreasonable restraint on competition. " *Id.* (citations omitted).

***6** Rockholt alleges Kincaid's and Rhode's activities were a *per se* violation of Section 1 of the Sherman Act. In light of the two basic distinctions in a distributor-termination case, this means the Court must find evidence of a concerted action to set prices.

In evaluating whether there is sufficient evidence of a concerted action to set prices, the Supreme Court has said "the fact that a manufacturer and its distributors are in constant communication about prices and marketing strategy does not alone show that the distributors are not making independent pricing decisions." *Id.* at 762. The Court explained, "A manufacturer and its distributors have legitimate reasons to exchange information about the prices and the reception of their products in the market." The Court also cautioned against inferring the parties have entered into a concerted agreement to set prices "merely from the existence of complaints, or even from the fact that termination came about ' *in response to'* complaints." *Id.* at 763 (emphasis added). As the Court explained, to infer an agreement based merely on evidence of this type " could deter or penalize perfectly legitimate conduct. " *Id.* The Court stated,

... complaints about price cutters "are natural-and from the manufacturer's perspective, unavoidable-reactions by distributors to the activities of their rivals." Such complaints, particularly where the manufacturer has imposed a costly set of nonprice restrictions, "arise in the normal course of business and do not indicate illegal concerted action." Moreover, distributors are an important source of information for manufacturers. In order to assure an efficient distribution system, manufacturers and distributors constantly must coordinate their activities to assure that their product will reach the consumer persuasively and efficiently. To bar a manufacturer from acting solely because the information upon which it acts originated as a price complaint would create an irrational dislocation in the market.

Id. at 763-764 (internal citations omitted).

The Supreme Court concluded, for there to be sufficient evidence of a concerted agreement to set prices, "something more than evidence of complaints is needed." *Id.* at 764. That something more "must be evidence that tends to exclude the possibility that the manufacturer and nonterminated distributors were acting independently.... [T]he antitrust plaintiff should present direct or circumstantial evidence that reasonably tends to prove that the manufacturer and others 'had a

conscious commitment to a common scheme designed to achieve an unlawful objective." ' *Id.* (citation omitted).

Rockholt contends there is sufficient evidence to meet the "something more" standard delineated by the Supreme Court. Rockholt contends the following provide sufficient evidence of a concerted action to set prices:
• Rhodes's complaints to Kincaid about Rockholt's prices;
*7 • Kincaid relayed these complaints to Rockholt to encourage Rockholt to raise its prices to a 42% margin-the specific profit margin Rhodes desired; [FN4]

FN4. *See* footnote number 2.

• Dennis Kincaid never told Calvin Rockholt that the reason he was terminated as a Kincaid distributor was because of the construction of the bridge between Decatur and Dayton and the establishment of a Kincaid gallery at Morgan Furniture;
• Sam Morgan, owner of Morgan Furniture, testifies Kincaid never informed him the establishment of a Kincaid gallery at his store would impact upon Rockholt; and
• Kincaid cannot agree upon who made the decision to terminate Rockholt as a distributor.[FN5]

FN5. Rockholt alleges Robert Lemons testified Dennis Kincaid made the decision to terminate Rockholt. Rockholt contends this testimony is inconsistent with Dennis Kincaid's testimony that "[He] could not veto the decision" (Rockholt's Response to the Motions for Summary Judgment, pp. 10-11). However, a review of the deposition excerpts reveals Roberts Lemons actually testified that Mr. Kincaid initiated the decision to terminate Rockholt and Lemons approved the decision (Lemons Depo. Excerpts I, p. 57). This testimony is consistent with Mr. Kincaid's description of the termination decision (D. Kincaid Depo., pp. 110-111). Thus, Rockholt's contention is not supported by the evidence.

(Rockholt's Response to the Motions for Summary Judgment, p. 10).

Even if the Court assumes, *arguendo,* there is sufficient evidence to support Rockholt's contentions,[FN6] this evidence does not lead to the inference there has been a violation of Section 1 of the Sherman Act. Rockholt has not cited, nor is the Court aware of, any authority which requires Kincaid to inform Rockholt or even a different distributor, such as Morgan Furniture, of its specific reasons for a termination. Furthermore, this failure, if true, is not circumstantial evidence "that reasonably tends to prove that the manufacturer *and others* 'had a conscious commitment to a unlawful objective" 'as is required by the Supreme Court's decision in *Monsanto.* The Supreme Court was clear in stating, Section 1 of the Sherman Act does not proscribe independent action. *Monsanto,* 465 U.S. at 761. To prove a violation, the Court must be presented with evidence of some *concerted* action by Rhodes and Kincaid and Rockholt has not met this burden. The Court reaches the same conclusion with respect to Rockholt's contention that Kincaid cannot agree on who made the decision to terminate Rockholt.[FN7]

FN6. *See* footnote numbers 2 and 5.

FN7. *See* footnote number 5.

This means the only evidence Rockholt has to support concerted action by Kincaid and Rhodes to set prices is Rockholt's contention Rhodes complained about Rockholt's prices and, in response to those complaints, Kincaid attempted to encourage Rockholt to raise its prices to the 42% profit margin desired by Rhodes. However, the *Monsanto* decision makes clear "something more" than evidence of this type is necessary to establish a Section 1 violation of the Sherman Act. Accordingly, the Court will GRANT Kincaid's and Rhodes's Motions for Summary Judgment on this

issue.

B. Tennessee State Antitrust Law, *Tenn.Code Ann.* §§ 47-25-101 and -102

"The State [of Tennessee] anti-trust statute passed in 1891 is quite similar to the Sherman Anti-Trust Act passed by Congress in 1890. Authorities which define the character of private damage suits under the federal anti-trust statutes, particularly the Sherman Act, are most persuasive." *State of Tennessee v. Levi Strauss & Co.*, 1980 WL 4696 at n.2 (Tenn. Ch. Ct. Sept. 25, 1980) (internal citation omitted). In Section III(A) of this Memorandum, the Court concluded Rockholt has not presented sufficient evidence to support its claim of a Sherman Act violation. For the same reasons, the Court concludes Rockholt's evidence fails with respect to any claim under the state antitrust law. [FN8] *See also Bailey's Inc. v. Windsor America, Inc.*, 948 F.2d 1018, 1032 (6th Cir.1991).[FN9] Accordingly, the Court will GRANT Kincaid's and Rhodes's Motions for Summary Judgment with respect to this issue.

FN8. Rockholt relies on the same evidence to support both its federal and state antitrust claims (Rockholt's Response to the Motions for Summary Judgment, p. 9).

FN9. In *Bailey's*, the plaintiff opposed summary judgment as to its contract, federal antitrust, and state antitrust claims. The plaintiff's brief in opposition to the motion for summary judgment, however, " was devoted almost exclusively to [the] contract and federal antitrust issues." *Bailey's*, 948 F.2d at 1032. With respect to the Tennessee state antitrust claim, the plaintiff merely quoted the statute and stated, "The comments made above concerning the federal antitrust laws are also applicable to the Tennessee antitrust laws." *Id.*
The district court found the plaintiff had failed to present sufficient evidence of a Sherman Act violation. The district court then also granted summary judgment on plaintiff's state antitrust claims "indicating that the plaintiff has no case under the state statutes for reasons similar to those given for the conclusion that the plaintiff has no case under federal antitrust law." *Id.* The Sixth Circuit affirmed both these rulings.

C. Breach of Contract

***8** For the Court to find there has been a breach of contract, the Court must first find there was a contract between Rockholt and Kincaid.[FN10] As detailed in Section II of this Memorandum, Calvin Rockholt testified the contract was oral and the terms were essentially "if you pay your bills and do a decent job of representing the product, people would continue to sell to you" (Calvin Rockholt Depo. Excerpts I, p. 56). With respect to any assent to the contract by Kincaid, Calvin Rockholt testified as follows:

FN10. Rockholt does not allege Rhodes was a party to any contract. Thus, Rhodes would be entitled to summary judgment on this issue.

Q: Okay. Well, tell me as near as you can exactly what it was that Dennis Kincaid said to you that you base this allegation that you have an agreement with Kincaid on.
A: When Dennis and I would work together, obviously he wanted me to buy more product and expand it within my store. And we were adding more product line, continually. And Dennis had even made the comment about, you know, that we paid our bills good and everything. And that was-
Q: He made what comment, now?
A: Well, that we paid our bills good and we were never late. And so we took that to the agreement [sic].
Q: I mean what did Dennis say? Did he say we will agree that we will not-that we'll continue to sell you Kincaid for an indefinitie period of time if you pay your bill on time?
A: No, Dennis didn't say that. That's a mutual understanding within the industry.

Id. at p. 57.

"In order to enforce a contract in Tennessee, the contract must result from a meeting of the minds, must be based upon sufficient consideration, and must be sufficiently definite to be enforced." *Peoples Bank of Elk Valley v. ConAgra Poultry,* 832 S.W.2d 550, 553 (Tenn.Ct.App.1991). Calvin Rockholt's testimony establishes there was not a meeting of the minds with respect to this alleged contract.

Rockholt's claim of a contract with Kincaid also fails because the contract, as described by Calvin Rockholt, permitted Mr. Rockholt to terminate performance at any time and for any reason yet Kincaid's would have had to perform for a potentially indefinite period. Finally, any alleged contract would likely run afoul of the statute of frauds.[FN11] Since the contract appears to involve the sale of goods over $500, the Uniform Commercial Code states the contract is not enforceable "unless there is some writing or record sufficient to indicate that a contract for sale has been made between the parties...." *Tenn.Code Ann.* § 42-2-201.[FN12] The parties did not sign a written contract and there has not been sufficient evidence of a "record" of a contract between Rockholt and Kincaid. Accordingly, the Court will GRANT Kincaid's and Rhodes's Motions for Summary Judgment on this issue.[FN13]

FN11. Rockholt did not address Defendants' arguments regarding the statute of frauds.

FN12. In 1997, the Tennessee legislature modified § 47-2-201 to state there must be either a writing or *record* of a contract for the contract to be enforceable.

FN13. *See* footnote number 10.

D. Unlawful Inducement of Breach of Contract, *Tenn.Code Ann.* § 47-50-109

In order to establish a cause of action for unlawful inducement of breach of contract under *Tenn.Code. Ann.* § 47-50-109, "a plaintiff must prove that there was a legal contract, of which the wrongdoer was aware, that the wrongdoer maliciously intended to induce a breach, and that as a proximate result of the wrongdoer's actions, a breach occurred that resulted in damages to the plaintiff ." *Quality Auto Parts v. Bluff City Buick,* 876 S.W.2d 818, 822 (Tenn.1994). In Section III(C) of this Memorandum, the Court concluded there was insufficient evidence to establish a contract between Rockholt and Kincaid and consequently, there was insufficient evidence of any breach of contract. Furthermore, even if the Court assumes, *arguendo,* there was a contract and a breach, Rockholt has failed to present any evidence Rhodes was even aware of any such contract (*See* Calvin Rockholt Depo. Excerpts I, p. 140 (Mr. Rockholt testified he did not have any indication Rhodes was aware of any contract between Rockholt and Kincaid); Stan Lowenstein Affidavit, ¶ 6, Supplemental File to Court File No. 29, Exh. E (Lowenstein was the manager of Rhodes from November, 1993 to October, 1994 and was not aware of any such contract); David Wallace Affidavit, ¶ 5, Supplemental File to Court File No. 29, Exh. G (Wallace was the manager of Rhodes from October, 1994 to February, 1996 and was not aware of any such contract)). Accordingly, the Court will GRANT Kincaid's and Rhodes's Motions for Summary Judgment on this issue. [FN14]

FN14. Under § 47-50-109, "[a] party to a contract cannot be held liable for procuring the breach of that contract." *Purisch v. Tennessee Technological University,* 76 F.3d 1414, 1420 (6th Cir.1996) (*citing Ladd v. Roane Hosiery, Inc.,* 556 S.W.2d 758, 760 (Tenn.1977). Since Rockholt's claim under § 47-50-109 is based on an alleged contract between Rockholt and Kincaid, Kincaid could not be liable for a violation of § 47-50-109 and would also be entitled to summary judgment.

E. Tortious Interference with Prospective Business Advantage

***9** Tennessee does not recognize a cause of action for interference with a prospective business advantage. *Nelson v. Martin,* 958 S.W .2d 643, 646 (Tenn.1997).[FN15] Accordingly, the Court will GRANT Kincaid's and Rhodes's Motions for Summary Judgment with respect to this issue.

FN15. Rockholt did not address this issue in its Response to the Motions for Summary Judgment.

F. Conspiracy

"A civil conspiracy is a combination between two or more persons to accomplish by concert an unlawful purpose, or to accomplish a purpose not in itself unlawful by unlawful means. The requisite elements of the cause of action are common design, concert of action, and an overt act. Injury to person or property, resulting in attendant damage, must also exist." *Menuskin v. Williams,*-F.3d-,-, 1998 WL 238625, at *13-14 (6th Cir. May 14, 1998) (*citing Braswell v. Carothers,* 863 S.W.2d 722, 727 (Tenn.Ct.App.1993). Rockholt's entire argument with respect to this claim is as follows:
It is unlawful for the Defendants to agree to accomplish unlawful purposes. As demonstrated above, the termination of Rockholt under these circumstances is an unlawful purpose, which has been accomplished by the concerted action of Rhodes and Kincaid.

(Rockholt's Response to the Motions for Summary Judgment, p. 12).

In Section III(A) of this Memorandum, the Court found insufficient evidence of a concerted action by Rhodes and Kincaid to set prices. In Sections III(B)-(E), the Court found insufficient evidence to establish any of Rockholt's other claims. Thus, there is no evidence of concerted action to accomplish *any* unlawful purpose. Accordingly, the Court will GRANT Kincaid's and Rhodes's Motions for Summary Judgment with respect to this issue.

IV. *CONCLUSION*

The Court concludes Rockholt has failed to present sufficient evidence to support its claims under Section 1 of the Sherman Act and the Tennessee State Antitrust Law. The Court also finds Rockholt has failed to present sufficient evidence to supports it claims for breach of contract, unlawful inducement of breach of contract, tortious interference with prospective business advantage, and conspiracy. For these reasons, the Court will GRANT Kincaid's and Rhodes's Motions for Summary Judgment. There being no other issues, the Court will also ORDER the case DISMISSED.

An Order shall enter.

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Rockholt Furniture, Inc. v. Kincaid Furniture Co., Inc.
Not Reported in F.Supp., 1998 WL 1661384 (E.D.Tenn.)

Briefs and Other Related Documents (Back to top)

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